

C 5 ECONOMIC ASPECTS OF ACUTE LIMB ISCHAEMIA

Compared with the management of critical limb ischaemia, the investigations and treatments of ALI have been subjected to very few economic analyses, possibly because of the urgency and the limited number of therapeutic options. The economic data on amputation is presented in Economic Aspects of Critical Limb Ischaemia, D 5, p S232.

The health care costs of treating an occlusion in an isolated native peripheral artery were estimated by Janosik et al¹ and Ourielet al,² from several retrospective series of patients treated with either thrombolytic therapy, with urokinase or streptokinase, or surgical thrombectomy. Only the costs of the initial admission were included, and hospital charges were used as a proxy for costs. Comorbid conditions were not documented. The most striking results are the convergence of economic data calculated between 1990 and 1993 that show similar mean charges. These range from \$20,000 (EUR 18,600) to \$26,000 (EUR 24,180) for all three treatments. Patients treated with urokinase have shorter length of stay but higher drug charges. However, the relevance of the comparison is limited by the fact that these were retrospective studies. Thus, it appears that when considering different strategies for thrombectomy, cost is not a decision criterion.³ A similar figure of \$25,000 (EUR 23,250) for thromboembolism was found by Hoch et al⁴ in 1994, who reported higher costs of \$45,000 (EUR 41,850) and worse results when urokinase was used as well in the procedure. Lower costs of surgical revascularisation were found by Singh et al in a 1993 to 1995 study in the United Kingdom. Their \$6,617 (EUR 6,154) cost per patient included the cost of the initial procedure and a 12-month follow-up.⁵ This study did not compare surgery with other treatments.

Thus, the choice between surgery and thrombolysis for ALI should not be based on economic factors but rather on predicted best clinical outcome. This is because both treatments have similar hospital costs in one study, whereas surgery is the better option in terms of results and lower costs from another study. (See Results of Surgical and Endovascular Procedures for Acute Limb Ischaemia, C 4.4, p S132, for analysis of the conflicting data comparing catheter-directed thrombolysis and surgery for ALI.)

Critical Issue 26: Economic data on acute limb ischaemia

There is a need for prospective studies documenting the costs of treating patients with acute limb ischaemia. To add significant data to this field, future studies should

- Define the duration and severity of ischaemia
- Specify the aetiology (thrombus/embolus)
- Prospectively compare, with randomisation, the therapeutic options
- Document the use of resources (see Recommendation 7)

References

1. Janosik JE, Bettmann MA, Kaul AF, Souney PF. Therapeutic alternatives for subacute peripheral arterial occlusion; *Invest Radiol* 1991; 26: 921-925.
2. Ouriel K, Shortell CK, DeWeese JA, Green RM, Francis CW, Azodo M, et al. A comparison of thrombolytic therapy with operative revascularization in the initial treatment of acute peripheral arterial ischaemia. *J Vasc Surg* 1994; 19: 1021-1030.
3. Kaul A. Pharmacoeconomic considerations in peripheral arterial thrombolytic therapy. *JVIR* 1995; 6: S104-S110.
4. Hoch JR, Tullis MJ, Archer CW, Heisey DM, Crummy AB, McDermott JC, et al. Thrombolysis versus surgery as the initial management for native artery occlusion: efficacy, safety, and cost. *Surgery* 1994; 16: 649-657.
5. Singh S, Evans L, Datta D, Gaines P, Beard JD. The costs of managing lower limb-threatening ischaemia. *Eur J Vasc Surg* 1996; 12: 359-362.

C 6 CLINICAL TRIAL ISSUES IN ACUTE LIMB ISCHAEMIA

The appropriate treatment of acute limb ischaemia is difficult to extract from the literature. This is because of individual or institutional reports of the results of both surgical and thrombolytic treatment either containing bias or not comparing with concurrent controls or not using standardised reporting practices. It is also because several recent trials comparing these two modalities have, in retrospect, been seen to have serious flaws. Conversely, now that these are apparent, guidelines for future trials can be developed that should further clarify the proper selection of patients for treatment and the treatment of choice in specific settings. The following are some of the critical issues in designing a trial in ALI, with examples of the problems that have been encountered in the past.